

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. 03N-0168]

*DHB*  
Display Date \_\_\_\_\_  
Publication Date \_\_\_\_\_  
Certifier *SLC*

**Current Status of Useful Written Prescription Drug Information for  
Consumers: Public Meeting**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of public meeting; request for comments.

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**SUMMARY:** The Food and Drug Administration (FDA) is announcing a public meeting to discuss the current status of the private sector's efforts to provide useful written prescription drug information to consumers. Public Law 104-180 adopted a goal that useful written information would be distributed to 75 percent of individuals receiving new prescriptions by the year 2000. An FDA-commissioned study of written information disseminated during 2001 with four widely-used prescription drugs reported the average "usefulness" of the information was only about 50 percent. The statute's goal for 2006 is that 95 percent of individuals receiving new prescriptions would receive useful written information. FDA is soliciting comments on and convening a public meeting to discuss what steps can be taken to improve the usefulness of such written prescription drug information in order to meet the year 2006 goal. FDA is posing four specific questions, and the agency is interested in responses to these questions and any other pertinent information stakeholders would like to share.

*Date and Time:* The public meeting will be held on July 31, 2003, from 9 a.m. to 5 p.m. Registration to speak at the meeting must be received by June

30, 2003. Written or electronic comments will be accepted to the docket until September 2, 2003.

*Location:* The public meeting will be held at the National Transportation Safety Board Boardroom and Conference Center, 429 L'Enfant Plaza, SW., Washington, DC 20594. (Phone: 202-314-6421; Metro: L'Enfant Plaza station on the green, yellow, blue, and orange lines). See: <http://www.nts.gov/events/newlocation.htm>. (FDA has verified the Web site address, but FDA is not responsible for any subsequent changes to the Web site after this document publishes in the **Federal Register**.)

*For Information Regarding This Notice Contact:* Christine Bechtel, Center for Drug Evaluation and Research (HFD-006), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-594-5458, email [bechtelc@cder.fda.gov](mailto:bechtelc@cder.fda.gov). If you need special accommodations due to a disability, please inform the contact person.

*Registration and Requests for Oral Presentation:* No registration is required if you only plan to attend the meeting. Seating will be on a first-come, first-served basis. If you wish to make an oral presentation during the open public comment period of the meeting, you must register to speak at the meeting by submitting your name, title, business affiliation, address, telephone number, fax number, and e-mail address and you must specify on your registration that you wish to make a presentation. You must also submit the following: (1) A written statement for each question addressed, (2) the names and addresses of all who plan to participate, and (3) the approximate time requested to make your presentation. Individuals who register to make an oral presentation will be notified of the scheduled time for their presentation prior to the meeting. Depending on the number of presentations, FDA may have to limit the time

allotted for each presentation. All participants are encouraged to attend the entire day. Presenters must submit two hard copies of each presentation given.

*For Registration Information Contact:* Christine Bechtel, Center for Drug Evaluation and Research (HFD-006), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-594-5458, email [bechtelc@cder.fda.gov](mailto:bechtelc@cder.fda.gov). Electronic registration for this meeting is available at: <http://www.accessdata.fda.gov/scripts/oc/dockets/meetings/meetingdocket.cfm>, or, registration requests and materials can be sent to Christine Bechtel.

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background**

Access to useful written patient information is an important aspect of helping to ensure appropriate use of prescription medicines, thereby preventing serious personal injury and avoiding excess costs to consumers and the health care system. FDA telephone surveys have shown that the rate of distribution of written prescription drug information has increased over the past 20 years.

Historically, written patient information has either been required by regulation for particular prescription drug products or product classes, or has been distributed on a voluntary basis by the manufacturer. Since 1968, FDA has occasionally required that prescription drug labeling written specifically for patients in nontechnical language be distributed to patients whenever certain prescription drugs, or classes of prescription drugs, are dispensed. In the 1970s, FDA began evaluating the usefulness of patient labeling for prescription drug products generally, and published a proposed rule to require written patient information for prescription drugs in 1979 (44 FR 40016, July

6, 1979). In 1980, FDA published a final rule establishing requirements and procedures for the preparation and distribution of FDA-approved patient labeling for a large number of prescription drugs (45 FR 60754, September 12, 1980). FDA revoked those regulations in 1982 based, in part, on assurances by the private sector that the goals of the final rule would be met (47 FR 39147, September 7, 1982). A decision was made to allow voluntary private sector initiatives to proceed before a determination was made whether to impose a mandatory program.

In 1995, FDA published a proposed rule entitled “Prescription Drug Product Labeling; Medication Guide Requirements” that would have required manufacturers to prepare and distribute “Medication Guides” to accompany a limited number of prescription drug products that posed a serious or significant public health concern, and set forth the requirements for the Medication Guide program (the 1995 proposed rule) (60 FR 44182, August 24, 1995). FDA’s proposed goal for prescription drugs that did not require Medication Guides was that, by the year 2000, at least 75 percent of people receiving new prescriptions would receive useful written patient information, and that by 2006, 95 percent of people who receive new prescriptions would also receive useful written patient information. The 1995 proposed rule set criteria by which written information would be judged to determine whether it was “useful” and should therefore count toward accomplishment of the target goals. FDA defined “useful” as written in nontechnical language and containing a summary of the most important information about the drug. FDA also specified that the usefulness of written patient information would be evaluated according to its scientific accuracy, consistency with a standard

format, nonpromotional tone and content, specificity, comprehensiveness, understandable language, and legibility.

On August 6, 1996, as FDA was reviewing the public comments on the 1995 proposed rule, Public Law 104–180 that adopted goals consistent with the 1995 proposed rule for the distribution of useful written patient information by the private sector, was enacted. The legislation also required that, no later than 30 days after its enactment, the Secretary of the Department of Health and Human Services (DHHS) (the Secretary) would request that national organizations representing health care professionals, consumer organizations, voluntary health agencies, the pharmaceutical industry, drug wholesalers, patient drug information database companies, and other relevant parties collaborate to develop a long-range comprehensive action plan (Action Plan) to achieve goals consistent with the goals of the 1995 proposed rule. Required elements of the Action Plan included: an assessment of the effectiveness of the current private-sector approaches to providing consumer medication information; the development of guidelines for providing effective consumer medication information consistent with the findings of such assessment; the identification of components necessary to ensure the transmittal of useful information to the public expected to use the product, including the criteria identified in the 1995 proposed rule; and the development of a mechanism to periodically assess the quality of prescription information and the frequency with which it is provided to consumers.

Under subsection (d) of section 601 of Public Law 104–180, FDA could not implement the portion of the proposed rule, or any other regulation or guideline, that specified a uniform, FDA-approved content or format for written information voluntarily provided to consumers about prescription

drugs, if private sector organizations met the requirements of the long-range Action Plan within the timeframe provided by the law.

The law also required DHHS to review the status of the private sector initiatives designed to achieve the goals of the action plan by January 1, 2001. Public Law 104–180 required that if 75 percent of individuals receiving new prescriptions did not receive useful written information by the year 2000, the limitation in subsection (d) of section 601 would not apply and the Secretary was required to seek public comment on other initiatives that could meet the goals.

Initially following the enactment of Public Law 104–180, the Secretary asked the Keystone Center to convene a Steering Committee to collaboratively develop the Action Plan. The Action Plan accepted by the Secretary in January 1997 reiterated the target goals specified in Public Law 104–180. The Action Plan endorsed the criteria specified in Public Law 104–180 for defining the usefulness of medication information. Specifically, the Action Plan stated that such materials should be: (1) Scientifically accurate; (2) unbiased in content and tone; (3) sufficiently specific and comprehensive; (4) presented in an understandable and legible format that is readily comprehensible to consumers; (5) timely and up to date; and (6) useful, that is, enables the consumer to use the medicine properly and appropriately, receive the maximum benefit, and avoid harm. [The Action Plan, including descriptions of the criteria, is available on the Internet at <http://www.keystone.org>. (FDA has verified the Web site address, but FDA is not responsible for any subsequent changes to the Web site after the document publishes in the **Federal Register**.)

Consistent with Public Law 104–180, the Action Plan called for the development of a mechanism to periodically assess the quality of written prescription information provided to patients. To test a methodology for collecting patient information materials and assessing their usefulness, FDA contracted with the National Association of Boards of Pharmacy (NABP). The contract called for the selection of several State Boards of Pharmacy, which would arrange for collecting, from a sample of State pharmacies, written materials given to patients when new prescriptions for three commonly prescribed drugs were filled. The contract also called for the development of an expert panel to create evaluation materials to assess the usefulness of the information through application of the Action Plan criteria. The written prescription drug information was collected in 1999, and the final report from the pilot study was completed in December 1999 and presented by FDA at a public workshop on February 29-March 1, 2000.

In 2001, FDA commissioned NABP to subcontract a national study to assess the usefulness of written prescription drug information being distributed to patients. A professional shopper firm was hired to bring prescriptions for four widely prescribed drugs in different drug classes to 384 pharmacies selected in a statistically random fashion from a national list. All written materials received with the prescriptions were sent to an expert panel for evaluation against the criteria endorsed by the Action Plan. The results of the study were announced in 2002. The evaluation found that, on average, 89 percent of patients received some form of written medication information. However, the expert panel found that the average “usefulness” of the information was only about 50 percent. The report of the evaluation is available at <http://www.fda.gov/cder/reports/prescriptioninfo/default.htm>.

The report findings were presented at an FDA Drug Safety and Risk Management Advisory Committee (the Advisory Committee) meeting on July 17, 2002. The Advisory Committee recommended that FDA take a more active role in advising and encouraging the private sector to meet the 2006 goal. FDA accords the recommendations of all advisory committees significant weight, but such recommendations are not binding on the agency. A transcript of FDA's Drug Safety and Risk Management Advisory Committee meeting on July 17, 2002, is available at <http://www.fda.gov/ohrms/dockets/ac/02/transcripts/3874T1.htm>.

## **II. Scope of Discussion**

In view of the facts described in section I of this document, FDA is soliciting comments on several issues and is convening this public meeting on July 31, 2003, to discuss the current status of the private sector's efforts to provide useful written prescription drug information to consumers. Interested persons are invited to submit comments to the docket and to attend the public meeting and present their views. Issues that we are asking interested parties to address in their comments, at the public meeting, or both, are as follows:

1. What steps is the private sector taking to improve the usefulness of the written information patients receive with prescription drugs and to meet the Year 2006 goal?
2. What barriers exist for the private sector to meet the Year 2006 goal, and what plans exist to overcome these barriers?
3. What should the role of FDA be in assuring full implementation of the Action Plan to meet the Year 2006 goal?
4. What other initiatives should FDA consider for providing patients with useful written information about prescription drugs as endorsed by Public Law

104–180? Such initiatives could include the possibility of FDA requiring manufacturers to provide authorized dispensers with the means to distribute useful written information approved by FDA.

### **III. Comments**

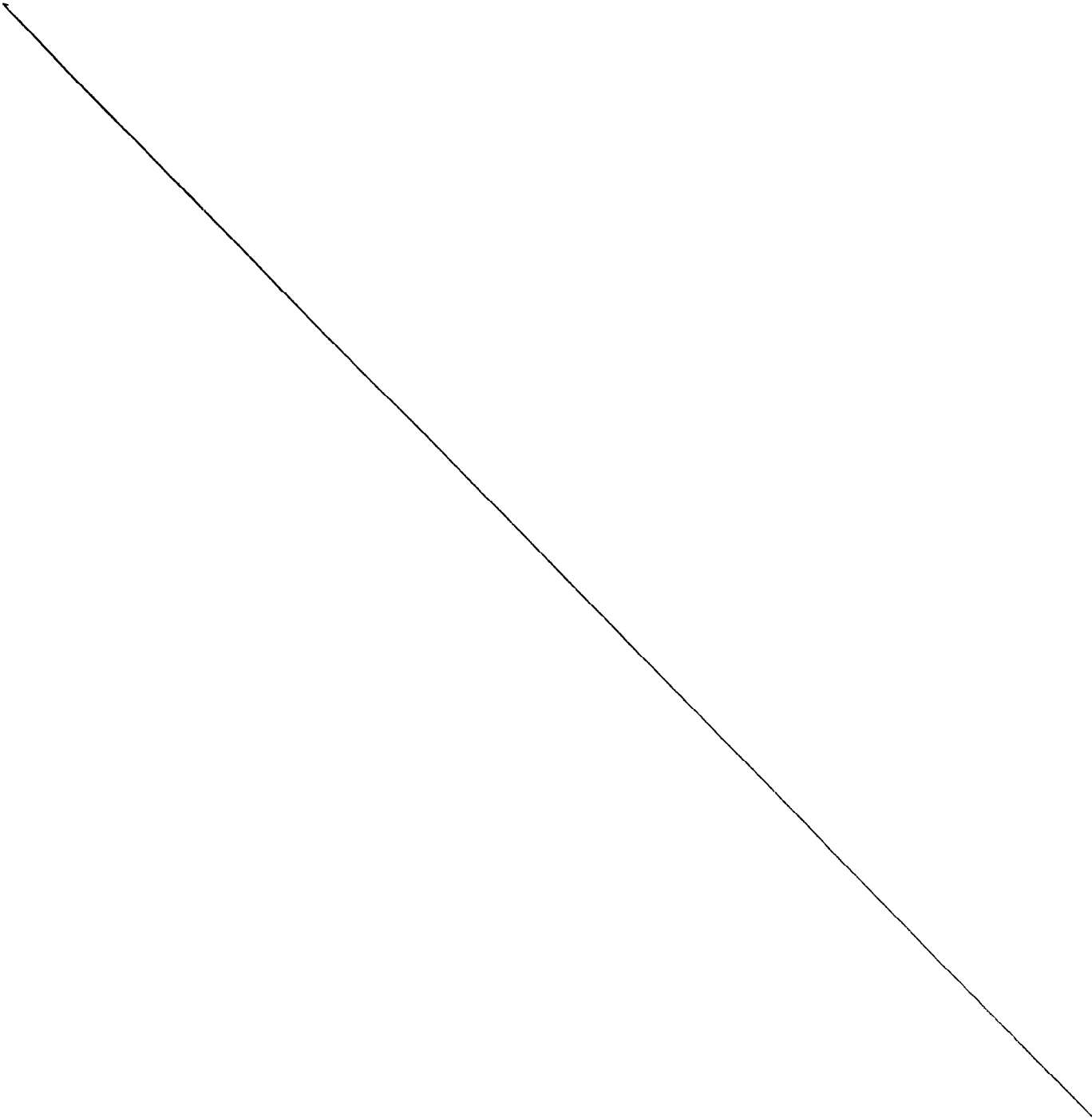
Interested persons may submit to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, written or electronic comments on or before September 2, 2003. You must submit two copies of comments, identified with the docket number found in brackets in the heading of this document. Submit electronic comments by September 2, 2003, to [fdadockets@oc.fda.gov](mailto:fdadockets@oc.fda.gov) or at <http://www.accessdata.fda.gov/scripts/oc/dockets/edockethome.cfm>. You should annotate and organize your comments to identify the specific questions to which they refer. Comments to the docket can be reviewed in the Dockets Management Branch, Monday through Friday between 9 a.m. and 4 p.m. or on the Internet at <http://www.fda.gov/ohrms/dockets/dockets/dockets.htm> (select docket # 03N–0168).

### **IV. Transcripts**

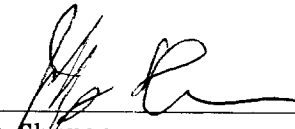
You may request a copy of the transcript in writing from the Freedom of Information Office (HFI–35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A–16, Rockville, MD 20857, approximately 15 days after the meeting at a cost of 10 cents per page. You may also examine the transcript Monday through Friday between 9 a.m. and 4 p.m. in the Dockets Management Branch or on the Internet at <http://www.fda.gov/ohrms/dockets/dockets/dockets.htm> (select docket # 03N–0168). The transcript will be available 4–6 weeks after the meeting.

**V. Electronic Access**

Persons with access to the Internet may obtain a copy of the commissioned study report at <http://www.fda.gov/cder/reports/prescriptioninfo/default.htm>, the Action Plan at <http://www.keystone.org>, and a transcript of FDA's July 17, 2002, Drug Safety and Risk Management Advisory Committee meeting at <http://www.fda.gov/ohrms/dockets/ac/02/transcripts/3874T1.htm>.



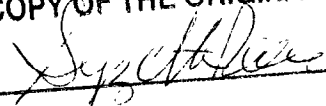
Dated: 5/22/03  
May 22, 2003.

  
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Jeffrey Shuren,  
Assistant Commissioner for Policy.

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